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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,226	09/16/2003	John R. Boehringer	2003-166	2118
23973 7590 10/04/2007 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,226	Applicant(s) BOEHRINGER ET AL.	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,30-33,35-38 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-29,34 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of group III, claims 23-29, 34 and 39 in the reply filed on July 9, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-22, 30-33, 35-38 and 40-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for priority from copending provisional Application No. 60/410,718, filed on September 16, 2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 2, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "material to examination" should instead read "material to patentability" and the citation of 37 C.F.R. 1.56(a) should instead cite 37 C.F.R. 1.56.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, 28 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Zamierowski (U.S. Patent No. 4,969,880).

With respect to **claim 23**: Zamierowski teaches a medical device for treating a wound by controlling the direction of wound contraction, comprising: suction means as disclosed in the form of suction bulb 42 for applying suction to the wound. The limitation "to facilitate contraction of the wound" constitutes functional language that is given little patentable weight herein. The instant device also comprises sealing means as disclosed in the form of flanges 19 and adhesive coating 30 on membrane skin contacting surface 28 of cover membrane 22 of wound dressing 10. The limitation "for maintaining suction on the wound by engaging the skin around the wound" constitutes functional language that is given little patentable weight herein. Wound packing means 10 for placement in the wound as disclosed is "preferably" anisotropic and "most preferably being a spirally wound...gauze". This phrase is interpreted as including equivalents

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thereof of the claimed wound packing means in accordance with 35 U.S.C. 112, sixth paragraph. Therefore the wound dressing 10 taught by Zamierowski anticipates the claimed invention in accordance with 35 U.S.C. 112, sixth paragraph.

With respect to **claim 24**: The packing means comprises Envinet mesh (i.e. gauze) as the absorbent material in a second embodiment shown in Figs. 9 and 10 of Zamierowski. (Col. 7, lines 53-55, Col. 8, lines 7-24)

With respect to **claim 28**: The suction means taught by Zamierowski comprises an apparatus adapted for manual compression, comprising a flexible bulb 42, with inlet conduit means in the form of suction tube 41 connecting the bulb 42 to the wound enclosure 22 and outlet conduit means 34 connecting the bulb to discharge in the form of pumping medication to wound site 12.

With respect to **claim 34**: The suction means 42 is a manual suction means, i.e. a bulb. (Col. 4, lines 41-44)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-27 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamierowski ('880) in view of Valentine et al (U.S. Patent No. 5,447,505).

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With respect to **claim 25**: Zamierowski does not teach any particular packing means and thus does not teach the packing means as disclosed or any equivalent thereof. Valentine teaches a wound dressing comprising rolls of gauze and teaches that such rolls are known in the art for their use as wound absorbent material. The additional layers of gauze provide additional absorbent capacity while decreasing the size of the gauze, therefore it would be obvious to one of ordinary skill in the art to modify the article of Zamierowski such that the wound dressing material 10 comprises the packing means as claimed with a reasonable expectation of success to provide increased absorbent capacity with smaller gauze. With regard to the limitation of "a gaze roll configuration having a generally longitudinal axis and radial axes, to be disposed in the wound with its longitudinal axis facing outside the wound and its radial axes facing sides of the wound", while Zamierowski does not explicitly teach such configuration, it would be obvious with a reasonable expectation of success to modify the article of Zamierowski and Valentine to arrive at the claimed invention, as there are only a finite number of possible arrangements of the gauze cylinders that would meet the design need of fitting in a wound site. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) ('505, Col. 6, lines 55-69)

With respect to **claim 26**: Zamierowski does not teach that the packing means comprises a plurality of said cylindrical gauze configurations, to be disposed generally parallel to each other in the wound. However it would be obvious to one of ordinary skill in the art to modify the article

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of Zamierowski and Valentine so as to meet this claim limitation with a reasonable expectation of success to ensure full coverage of the wound site. It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977) ('505, Col. 6, lines 55-69)

With respect to **claim 27**: The packing means of the combined teaching of Zamierowski and Valentine comprises generally spirally wound gauze configuration(s), i.e. gauze roll configurations. ('505, Col. 6, lines 55-69)

With respect to **claim 39**: Zamierowski teaches a method of controlling the direction of contraction of a wound comprising the steps of: (a) placing a wound packing means 10 in a wound 12 in a predetermined orientation; (b) sealing the wound via flanges 19 and adhesive 30 thereon; and (c) applying suction to the wound via suction bulb 42.

Zamierowski does not explicitly teach that the wound packing means is an anisotropic wound packing means. However the anisotropic wound packing means as disclosed comprises gauze, which is anisotropic by nature and known in the art for its use as wound packing material as supported by Valentine et al. Therefore it would be obvious to one of ordinary skill in the art to modify the method of Zamierowski such that the step of placing a wound packing means involves placing an anisotropic wound packing means as disclosed with a reasonable expectation of success to ensure that the wound packing material provides its intended function. ('505, Col. 6, lines 55-69)

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamierowski ('880) in view of McNeil (U.S. Patent No. 4,551,141).

With respect to **claim 29**: Zamierowski does not teach spring means inside the bulb. McNeil teaches that springs are an equivalent means of generating suction to bellows and bulbs in portable drainage devices, both of which are taught by Zamierowski, therefore it would be obvious to one of ordinary skill in the art to modify the suction means of Zamierowski so as to have a bulb with a spring means inside to supplement the suction-generating capability of the bulb as taught by McNeil. The limitation of "for providing resistance to rapid decay of suction in the bulb" constitutes functional language that is given little patentable weight herein. ('141, Col. 6, lines 59-62)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

September 27, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

